

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

_____)	
AVENTIS PHARMACEUTICALS INC. and)	
SANOFI-AVENTIS US LLC)	
)	
)	
Plaintiffs,)	C.A. No. 06-286 (GMS)
)	
v.)	
)	
BARR LABORATORIES, INC.)	
)	
Defendants.)	
_____)	

STIPULATED PROTECTIVE ORDER

WHEREAS Aventis Pharmaceuticals Inc., Sanofi-Aventis US LLC, and Barr Laboratories, Inc. are the parties to Civil Action No. 06-286 (GMS) (the “action” or “litigation”),

WHEREAS the parties and likely nonparty witnesses possess confidential information which may be disclosed in responding to discovery requests or otherwise in these action and which must be protected in order to preserve their legitimate business interests, and

WHEREAS the parties have, through counsel, stipulated to the entry of this Protective Order to prevent unnecessary dissemination or disclosure of such confidential information,

WHEREAS the parties have established good cause for entry of this Protective Order;
IT IS HEREBY ORDERED that:

Definitions

1. (a) The term “Confidential Information” as used in this Order includes, and shall be limited to, all information (other than information described in paragraph 1(b))

constituting, disclosing or relating to proprietary data or information that the designating party believes to be of commercial value, including but not limited to trade secrets. It may include, without limitation, documents produced in the actions, during formal discovery or otherwise; information of non-parties which the producing or designating party is under an obligation to maintain in confidence; initial disclosures; answers to interrogatories and responses to requests for admission or other discovery requests; deposition or hearing transcripts; affidavits; exhibits; experts' reports; memoranda of law; and tangible things or objects that are designated confidential pursuant to this order. The information contained therein and all copies, abstracts, excerpts, analyses, notes or other writings that contain, reflect, reveal or otherwise disclose such confidential information shall also be deemed "Confidential Information." Information originally designated as "Confidential Information" shall not retain that status after any ruling by the Court denying such status to it. Each party shall act in good faith in designating information as "Confidential Information."

(b) The term, "Highly Confidential Information" as used in this order includes, and shall be limited to, information that the designating party believes constitutes, discloses or relates to information regarding (i) unpublished pending patent applications, (ii) ongoing scientific research, including research relating to any product related to the litigation for which a party has filed a New Drug Application or Abbreviated New Drug Application, (iii) sales, costs, margins, profitability and expenses with respect to any product or process, (iv) future market or business plans or strategies for existing or new products or processes, including but not limited to competitive analyses, marketing strategies, and proprietary marketing tools, (v) details of proprietary processes for chemical syntheses that are relevant to any issue in this litigation, and (vi) information relevant to current or future regulatory submissions related and

unrelated to products at issue in this litigation or any predecessor products thereof. It may include, without limitation, documents produced in this action, during formal discovery or otherwise; information of non-parties which the producing or designating party is under an obligation to maintain in confidence; initial disclosures; answers to interrogatories and responses to requests for admission or other discovery requests; deposition or hearing transcripts; affidavits; exhibits; experts' reports; memoranda of law; and tangible things or objects that are designated highly confidential pursuant to this order. The information contained therein and all copies, abstracts, excerpts, analyses, notes or other writings that contain, reflect, reveal or otherwise disclose such highly confidential information shall also be deemed "Highly Confidential Information." Information originally designated as "Highly Confidential Information" shall not retain that status after any ruling by the Court denying such status to it. Each party shall act in good faith in designating information as "Highly Confidential Information."

(c) The term "party" means Aventis Pharmaceuticals Inc., Sanofi-Aventis US LLC, and Barr Laboratories, Inc.

(d) The term "designating party" means the party or nonparty designating documents or information as Confidential Information or Highly Confidential Information under this Order.

(e) The term "receiving party" shall mean the party to whom Confidential Information or Highly Confidential Information is produced.

Designation of Confidential Information or Highly Confidential Information

2. Each designating party who produces or discloses any material that it believes comprises Confidential Information may so designate it by marking the document containing the

information “CONFIDENTIAL.” Each designating party who produces or discloses any material that it believes comprises Highly Confidential Information may so designate it by marking the document containing the information “HIGHLY CONFIDENTIAL.” When documents are produced for inspection, the documents shall be treated by the inspecting party as “Highly Confidential” until copies are provided. Deposition testimony will be treated as Highly Confidential Information until ten (10) business days after receipt of the transcript unless, prior to the expiration of the ten (10) business days, the party providing the testimony waives confidentiality. To maintain the testimony as “Confidential” or “Highly Confidential,” no later than ten (10) business days after receiving the transcript, the designating party must indicate in writing the specific portions of the transcript (by page and line) it wishes to so designate.

3. If any Confidential Information or Highly Confidential Information is produced by a nonparty to these litigations, such a nonparty shall be considered a designating party within the meaning of that term as it is used in the context of this Order and each of the parties shall be treated as a receiving party. Confidential Information or Highly Confidential Information that originated with a nonparty and which is subject to a confidentiality obligation may be designated as such and shall be subject to the restrictions on disclosure specified herein.

4. In the event any designating party produces Confidential Information or Highly Confidential Information that has not been designated as such or not correctly designated, the designating party may designate or redesignate the information to the same extent as it may have designated the information before production, by a subsequent notice in writing specifically identifying the redesignated information, in which event the parties shall henceforth treat such information in accord with this Order, and shall undertake their best efforts to correct any disclosure of such information contrary to the redesignation, including retrieving any documents

from persons not qualified to receive them under the redesignation and informing such persons that they should not further use or disseminate the information thereon. No demonstration or proof of error, inadvertence, or excusable neglect by the designating party shall be required for such redesignation.

5. A party shall not be obligated to challenge the propriety of any designation of Confidential or Highly Confidential information at the time the designation is made, and failure to do so shall not preclude a subsequent challenge to the designation. In the event that any party to this action disagrees at any stage of this action with any designation, such party shall provide written notice of its disagreement with the designation to the Disclosing Party. The parties shall first try to dispose of such dispute in good faith on an informal basis. If the dispute cannot be resolved, the party challenging the designation may request appropriate relief from the Court within ten (10) business days after written notice is provided. The burden of proving that information has been properly designated is on the Disclosing Party. However, the parties agree that designating information as Confidential or Highly Confidential is improper if such information (i) can be shown to be generally available to the public at the time of such designation; (ii) becomes part of the public domain or publicly known or available by publication or otherwise not as the result of any unauthorized act or omission on the part of the non-designating party; or (iii) is thereafter disclosed to the non-designating party by a third party as a matter of right.

Disclosure and Use of the Confidential and Highly Confidential Information

6. (a) Subject to Paragraphs 12-15, Confidential Information may be disclosed, summarized, described, revealed or otherwise made available in whole or in part only in accordance with the terms of this Order, and only to the following persons:

- i. outside counsel of record for a party, and employees of such counsel;
- ii. one (1) designated in-house attorney employed by the Receiving Party and his or her clerical staff (including paralegals), who has a need to know Confidential and Highly Confidential information to fulfill his or her duties and responsibilities in connection with this litigation, provided such person has complied with Paragraph 12 hereof, the designated in-house attorney for the parties being as follows:

For Aventis and Sanofi-Aventis: Peter Dolan;

who, after receipt of Barr Confidential or Highly Confidential Information, and in addition to the other terms of this protective order, (A) shall not be involved in the preparation or prosecution of any patent application that covers any finished drug product containing TAA as active ingredient for the duration of the action including appeals, (B) shall not be involved in the preparation or submission of any petition to the FDA regarding approval requirements for any finished drug product containing TAA as active ingredient, and (C) shall not disclose to the FDA Barr's Confidential or Highly Confidential Information;

For Barr: Frederick Killion;

who, after receipt of Aventis or Sanofi-Aventis Confidential or Highly Confidential Information, and in addition to the other terms of this protective order, (A) shall not be involved in the preparation or prosecution of any patent application that covers any finished drug product containing TAA as active ingredient for the duration of the action including appeals, (B) shall not be involved in the preparation or submission of any petition to the FDA regarding approval requirements for any finished drug product containing TAA as active ingredient, and (C) shall not disclose to the FDA Aventis or Sanofi-Aventis Confidential or Highly Confidential

Information;

iii. independent experts and consultants and their staff (excluding current directors, officers or employees of the parties, but including former employees of the parties) retained to assist counsel for the parties in the conduct of this Litigation, provided such persons have complied with Paragraph 12 hereof;

iv. witnesses in these actions who are directors, officers, employees, or corporate designees under Fed. R. Civ. P. 30(b)(6), but only at deposition or trial;

v. potential witnesses in these actions (including, but not limited to, those who were formerly directors, officers, employees or experts of the designating party) and their counsel, provided that (a) the Confidential or Highly Confidential information was authored by, created by, received by, or is otherwise established to have been known to the witness; and (b) the witness complies with Paragraph 12, hereof; but only at deposition or trial;

vi. the Court and its employees and the jury;

vii. court reporters;

viii. photocopy services;

ix. professional translators who are retained by the attorneys for the parties for the purposes of these litigations;

x. graphics or design consultants retained to prepare demonstrative or other exhibits for use in these actions;

xi. non-technical jury or trial consultants and persons employed or retained by them;

xii. document imaging and database services and consultants retained to set up, maintain and/or operate litigation databases; and

xiii. others as to whom the designating party has given written consent.

(b) Subject to Paragraphs 12-15, Highly Confidential Information may be disclosed, summarized, described, revealed or otherwise made available in whole or in part only in accordance with the terms of this Order, and only to the persons described in Paragraph 6(a).

7. Nothing in this protective order shall prevent disclosure of Confidential or Highly Confidential Information if the designating party consents to such disclosure or if the Court, after notice to all parties, orders such disclosure.

8. All Confidential and Highly Confidential Information disclosed pursuant to this Order shall be used by a recipient thereof solely for the purposes of these litigations, and not for any business or competitive purposes. It shall be the duty of each party and each individual having notice of this Protective Order to comply with this Order from the time of such notice.

9. By written agreement of the parties, or upon motion and order of the Court, the list of individuals designated under paragraph 6(a)(ii) to whom Confidential and/or Highly Confidential Information may be disclosed may be modified or expanded.

10. If a party intends to reveal the Confidential Information or Highly Confidential Information of another party during a trial, court appearance or hearing which is open to the public (a "Court Disclosure"), the party seeking to make the Court Disclosure shall first make an application to the Court *in camera* to permit such use, unless consent from the designating party is previously obtained.

11. (a) All documents and things containing Confidential Information or Highly Confidential Information appropriately filed with the Clerk shall be in a sealed envelope or container on which shall be affixed the title of the actions, an indication of the nature of the contents, the words "[HIGHLY] CONFIDENTIAL - FILED UNDER SEAL" and a statement

substantially as follows:

**THIS ENVELOPE CONTAINS MATERIAL
SUBJECT TO A PROTECTIVE ORDER
ENTERED IN THIS ACTION. IT IS NOT TO
BE OPENED NOR ARE ITS CONTENTS TO
BE DISPLAYED, REVEALED OR MADE
PUBLIC, EXCEPT BY ORDER OF THE
COURT.**

The Clerk of the Court is directed to maintain under seal all documents and transcripts of deposition testimony and answers to interrogatories, admissions and other pleadings filed under seal that have been designated, in whole or in part, as Confidential or Highly Confidential Information.

(b) If any party fails to file documents or things containing Confidential Information or Highly Confidential information under seal, the designating party or any party to this action may request, within 30 calendar days of the filing of said designated materials, that the Court place the designated materials under seal. The Clerk of the Court is directed to comply with such request if made.

12. No person identified in Paragraphs 6(a)(ii), (iii) or (v) shall be provided access to designated information unless such person shall first have signed a Declaration of Compliance with this Order in the form attached as Exhibit A hereto.

13. Before any person identified in Paragraphs 6(a)(ii), (iii) or (v) may be given access to designated information, the party seeking to provide such access shall deliver a copy of the Declaration referred to in Paragraph 12, fully executed by such person, and written notice (by facsimile) to the attorneys for the designating party of the intention to make such disclosure. In the case of a disclosure to persons identified in Paragraph 6(a)(iii) hereof, the notice shall state the name and address of the person to whom disclosure is proposed and include a resume of the

background, qualifications and employment or affiliations of such person, including all prior engagements as a consultant or expert witness on behalf of any pharmaceutical company in the last 5 years. In the case of a disclosure to persons identified in Paragraph 6(a)(ii) hereof, the notice shall state the employee's name and position.

14. For proposed disclosures to persons identified in Paragraphs 6(a)(ii), (iii) and (v) hereof, the designating party, within ten (10) business days from receiving service of written notice provided pursuant to Paragraph 13 hereof, may object to such disclosure by delivery (by facsimile) of a written notice of objection on the attorneys for the party seeking to make the disclosure, stating the reasons for the objection. No disclosure of Confidential Information or Highly Confidential Information may occur prior to the expiration of ten (10) business days from the date of service of the written notice of intent to disclose unless consent is granted earlier by the designating party. Consent pursuant to the provisions of this paragraph shall not be unreasonably withheld. If the designating party objects to the disclosure and gives written notice thereof, and the parties are unable to resolve the objection, the designating party must file a motion for a protective order within ten (10) business days of giving the written notice of objection; otherwise, the information may be disclosed to the identified person. If such a motion is made, no disclosure may be made until the objection is resolved by agreement of the designating and receiving parties or the Court denies the motion. Failure to timely object to the disclosure based on information then-disclosed in the written notice pursuant to Paragraph 13 hereof shall operate as a waiver of the objection. However, a designating party shall not be precluded from objecting to the disclosure to such identified person if additional information is later disclosed by the receiving party or is obtained through subsequent discovery. Such a later objection must be made within ten (10) business days of the date the objecting party first learns

of the additional information.

15. Nothing herein shall prevent any party from disclosing its own Confidential Information or Highly Confidential Information in any manner that it considers appropriate.

16. Nothing herein shall bar or otherwise restrict counsel from rendering advice to his or her client with respect to this litigation and, in the course thereof, referring to or relying upon his or her examination of Confidential or Highly Confidential Information. In rendering such advice and in otherwise communicating with his or her client, counsel shall not disclose any Confidential or Highly Confidential Information if such disclosure would be contrary to the provisions of this protective order.

Duration of Order, Objections, Modifications

17. This Protective Order shall remain in force and effect indefinitely until modified, superseded or terminated by Order of this Court, which may be entered pursuant to agreement of the parties hereto. This Protective Order shall continue in effect after termination of all actions and continue to be binding upon all persons to whom Confidential Information or Highly Confidential Information is disclosed hereunder.

18. Upon final termination of these actions (including all appeals) the receiving party shall, within sixty (60) days of such termination, either return to the designating party or destroy all Confidential Information and Highly Confidential Information in its possession, including but not limited to information stored in electronic form. In either event, the receiving party shall describe the materials returned or destroyed and certify their return or destruction, with the exception that outside counsel may retain subject to the provisions of this Protective Order one copy of the pleadings or other papers filed with the Court or served in the course of the litigation, deposition transcripts, deposition exhibits and the trial record.

19. If the receiving party learns that Confidential Information or Highly Confidential Information produced to it has been disclosed to or has come into the possession of any person other than in the manner authorized by this Protective Order, the receiving party responsible for the disclosure must immediately inform the designating party of all pertinent facts relating to such disclosure and shall make every effort to prevent disclosure by each unauthorized person who received such information.

20. If the receiving party desires to disclose Confidential information or Highly Confidential Information to persons not qualified to receive it under this Order or if the receiving party disagrees with a designation by the designating party, then the receiving party and the designating party shall first try to resolve such dispute. If the dispute cannot be resolved, either party may seek a ruling from the Court. Pending a determination by the Court, such information shall be treated under this Order as Confidential Information or Highly Confidential Information as designated by the designating party.

No Waiver of Privileges

21. If information that is otherwise properly subject to a claim of attorney-client privilege, attorney work product immunity or any other legal privilege protecting it from discovery is inadvertently produced, the fact or circumstances of such inadvertent production shall in no way be relied upon as a ground to support any argument that the information is no longer subject to the privilege or immunity. Nor shall such inadvertent production prejudice or otherwise constitute a waiver of, or estoppel as to, any claim of privilege, work product immunity or other ground for withholding production to which the designating party or other person otherwise would be entitled. If a written claim of inadvertent production is made pursuant to this paragraph, with respect to information then in the custody of another party, upon

receipt of such written notice, such party shall promptly return to the claiming party or person (i) the inadvertently produced material, (ii) any and all copies or reproductions thereof, and (iii) any and all copies of summaries or notes based thereon or relating thereto, of which the receiving party is aware, unless the receiving party wishes to challenge the claim that the information would have properly been subject to a privilege or immunity before it was inadvertently produced. If the party receiving the inadvertently produced material wishes to make such a challenge, it must notify the producing party of its challenge within ten (10) business days of receiving the notice of inadvertent production, and move the Court for a ruling on the propriety of the claim of privilege or immunity within seventeen (17) business days of receiving the notice of inadvertent production. As stated, such motion shall not rely upon in any manner or assert as a ground for entering such an Order the fact or circumstances of the inadvertent production. During the pendency of such motion, the receiving party shall make no other use or disclosure of the subject material or the information contained therein. If the producing party prevails on its privilege or immunity claim, the receiving party shall promptly return the material and all copies or reproductions thereof of which it is aware and shall delete all references to or descriptions of the privileged information contained in any written materials. Once a document or information has been: used during a deposition; used as an exhibit to a pleading filed with the Court; identified for potential use at trial, including in discovery responses; or otherwise disclosed to the Court, the producing party has thirty (30) calendar days from the date of disclosure to provide notice of the inadvertent production. Notwithstanding any other provision of this protective order, failure to provide notice within this thirty-day period shall constitute a waiver of any and all applicable privileges and immunities with respect to the inadvertently produced documents or information only.

22. If any Confidential or Highly Confidential Information is disclosed through inadvertence or otherwise by a Receiving Party to any person or party not otherwise authorized to receive such information under this Protective Order, then the Receiving Party responsible for the disclosure shall (i) use its best efforts to obtain the return of such information and to bind such non-authorized person or party to the terms of this Protective Order; (ii) within three (3) days of the discovery of such disclosure, inform such person or party of all provisions of this Protective Order and request that such person or party sign the Declaration of Compliance with this Protective Order in the form attached as Exhibit A hereto; and (iii) within five (5) days of the discovery of such disclosure, inform the Producing Party of all pertinent facts relevant to such disclosure, including the identity of such person or party and the information disclosed thereto.

Other Remedies

23. Nothing herein shall prevent any party or nonparty from seeking additional or different relief from the Court not specified in this Order.

Miscellaneous

24. No party shall be responsible to another party for any use made of information that was produced and not designated as Confidential or Highly Confidential Information, except to the extent a party is required to perform the duties set forth in Paragraph 4 above.

25. Nothing in this protective order shall prejudice the right of any party to oppose production of any information for lack of relevance, privilege, or any ground other than confidentiality.

26. Nothing in this protective order shall prejudice the right of any party to seek at any time a further order modifying this protective order.

27. In the event that a new party is added, substituted, or brought in, this protective

order will be binding on and inure to the benefit of the new party, subject to the right of the new party to seek relief from or modification of this protective order.

28. Notice under this protective order shall be to the parties as follows, unless this provision is modified by the parties in writing and filed with this Court: notice to Plaintiffs shall be made to Joshua R. Rich and Jeremy E. Noe; notice to Defendant shall be to George C. Lombardi and Maureen L. Rurka, all at their respective addresses of record filed with this Court for this civil action.

Dated: August 18, 2006

ASHBY & GEDDES

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Attorneys for Defendant Barr Laboratories,
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SO ORDERED this ____ day of _____, 2006.

United States District Judge

EXHIBIT A

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

_____)	
AVENTIS PHARMACEUTICALS INC. and)	
SANOFI-AVENTIS US LLC)	
)	
)	
Plaintiffs,)	C.A. No. 06-286 (GMS)
)	
v.)	
)	
BARR LABORATORIES, INC.)	
)	
Defendants.)	
_____)	

DECLARATION OF COMPLIANCE

I, _____ do declare and state as follows:

1. I live at _____. I am employed as (state position)

_____ by (state name and address of employer)

_____.

2. I have read the Protective Order entered in this case, a copy of which has been given to me.

3. I understand and agree to comply with and be bound by the provisions of the Protective Order, including that upon receipt of any Confidential Information or Highly Confidential Information, I will be personally subject to it, and to all of its requirements and procedures.

4. I agree that I will be subject to the jurisdiction of the United States District Court

for the District of Delaware for purposes of enforcement of the Protective Order.

5. I understand that unauthorized disclosure of any designated Confidential or Highly Confidential Information, or its substance, may constitute contempt of this Court and may subject me to sanctions or other remedies that may be imposed by the Court and or potential liability in a civil action for damages by the disclosing party.

6. At the final termination of this litigation, I will return to counsel all documents or things consisting of or containing confidential information.

7. I declare, as provided by 28 U.S.C. Section 1746, under penalty of perjury, under the laws of the United States of America, that the foregoing is true and correct.

Executed this _____ day of _____, 200__.
